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By: Senators Montgomery and Forehand

Introduced and read first time: February 4, 2011

Assigned to: Finance

A BILL ENTITLED

1 AN ACT concerning 2 Health - Newborn Screening Program - Critical Congenital Heart Disease FOR the purpose of requiring that the Department of Health and Mental Hygiene's 3 Newborn Screening Program include screening for critical congenital heart 4 5 disease. 6 BY repealing and reenacting, with amendments, 7 Article – Health – General Section 13-111 8 Annotated Code of Maryland 9 (2009 Replacement Volume and 2010 Supplement) 10 11 Preamble 12 WHEREAS, Congenital heart disease is the most common birth defect and affects approximately eight out of every 1,000 infants each year; and 13 14 WHEREAS, More than 36,000 infants are born with congenital heart disease each year in the United States; and 15 16 WHEREAS, Congenital heart disease is the leading cause of death for infants 17 born with a birth defect despite survival rates now approaching 96% for all affected children; and 18 19 WHEREAS, A major cause of infant mortality as a result of congenital heart 20 disease is that a significant number of children affected are not detected as having 21heart disease in the newborn nursery; and 22WHEREAS, An effective newborn screening mechanism for congenital heart 23 disease before newborns leave the nursery can reduce infant mortality; and

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laboratory is required to perform;

$\frac{1}{2}$	WHEREAS, Pulse oximetry has been shown to be an effective screening test to detect congenital heart disease before infants leave the newborn nursery; and
3 4 5	WHEREAS, Children's National Medical Center has worked with Holy Cross Hospital to become leaders in the implementation of pulse oximetry screening in community nurseries; and
6 7 8 9	WHEREAS, The Secretary of Health and Human Services' Advisory Committee for Heritable Disorders in Newborns and Children recommended the addition of screening for critical cyanotic congenital heart disease to the core panel for universal screening of all newborns in the United States; now, therefore,
10 11	SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:
12	Article – Health – General
13	13–111.
14 15 16 17	(a) The Department shall establish a coordinated statewide system for screening all newborn infants in the State for certain hereditary and congenital disorders associated with severe problems of health or development, except when the parent or guardian of the newborn infant objects.
18 19 20 21	(b) Except as provided in § 13–112 of this subtitle, the Department's public health laboratory is the sole laboratory authorized to perform tests on specimens from newborn infants collected to screen for hereditary and congenital disorders as determined under subsection (d)(2) of this section.
22	(c) The system for newborn screening shall include:
23	(1) Laboratory testing and the reporting of test results; [and]
24 25	(2) Follow-up activities to facilitate the rapid identification and treatment of an affected child; AND
26	(3) SCREENING FOR CRITICAL CONGENITAL HEART DISEASE.
27 28	(d) In consultation with the State Advisory Council on Hereditary and Congenital Disorders, the Department shall:
29 30	(1) Establish protocols for a health care provider to obtain and deliver test specimens to the Department's public health laboratory;

Determine the screening tests that the Department's public health

$\frac{1}{2}$	(3) Maintain a coordinated statewide system for newborn screening that carries out the purpose described in subsection (c) of this section that includes:
3 4	(i) Communicating the results of screening tests to the health care provider of the newborn infant;
5	(ii) Locating newborn infants with abnormal test results;
6 7	(iii) Sharing newborn screening information between hospitals health care providers, treatment centers, and laboratory personnel; and
8 9	(iv) Delivering needed clinical, diagnostic, and treatment information to health care providers, parents, and caregivers; and
10 11 12	(4) Adopt regulations that set forth the standards and requirements for newborn screening for hereditary and congenital disorders that are required under this subtitle, including:
13	(i) Performing newborn screening tests;
14 15	(ii) Coordinating the reporting, follow—up, and treatment activities with parents, caregivers, and health care providers; and
16 17 18	(iii) Establishing fees for newborn screening that do not exceed an amount sufficient to cover the administrative, laboratory, and follow—up costs associated with the performance of screening tests under this subtitle.
19 20	SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effectfully 1, 2011.